7.

K091298

510(k) SUMMARY

FEB 2 4 2010

Applicant: Curves Limited
2 High Road
Eastcote
Pinner
Middlesex
HA5 2EW

Contact name: Nilufer Smith
Managing Director
Tel: +44 (0) 20 7371 6062

Date prepared: 20th March 2009

Proprietary name: Lubrease Female Lubricant

Common name: Personal lubricant

Classification name: Condom
Regulation Number (21 CFR 884.5300)
Procode (NUC)

Predicate devices:
Lubrease is considered to be substantially equivalent to Aquagel (K951431) and Rephresh (K021737).

Description of device:
Lubrease is a single use applicator containing 1.6ml water based lubricating gel. The applicator is designed to lock after the gel has been applied to prevent inadvertent re-use of the applicator.

Indications for Use:
Lubrease is intended to be used for immediate lubrication of vaginal dryness and relief from intimate discomfort. It is intended for discreet vaginal use as a moisturiser and lubricant immediately prior to sexual intercourse.

Technological characteristics:
The Lubrease gel is presented in a patented single use applicator. The formulation of the gel is proprietary but it consists of 95% water and the other ingredients are similar to those of the predicate devices.

8. Financial statement:

Curves Limited has not performed any clinical trials on Lubrease and there are consequently no financial implications to be considered in accordance with 21 CFR 54.

9. Submission statement:

I, Nilufer Smith, of Curves Limited, 2 High Road, Eastcote, Pinner, Middlesex, HA5 2EW, confirm that I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Signed: Nilufer Smith

Date: 22nd February 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2014

Mr. Nilufer Smith
Managing Director
Curves Limited
2 High Road Eastcote
Pinner, Middlesex HAS 2EW
UNITED KINGDOM

Re: K091298
Trade/Device Name: Lubrease Female Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated (Date on orig SE ltr): February 10, 2010
Received (Date on orig SE ltr): February 12, 2010

Dear Mr. Smith,

This letter corrects our substantially equivalent letter of February 24, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091298

Device Name: Lubrease Female Lubricant

Indications for Use:

Lubrease is a personal lubricant for vaginal application, intended to moisturise and lubricate to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.
This product is NOT compatible with latex or synthetic condoms

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091298